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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,654

05/01/2006

Omry Ben-Ezra

75632/JPW/JW

2254

23432 7590 07/30/2010
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EXAMINER

DIETRICH, JOSEPH M

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

07/30/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,654	Applicant(s) BEN-EZRA ET AL.	
	Examiner Joseph M. Dietrich	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-25,30-45,164-168,173-188 and 361-364 is/are pending in the application.
- 4a) Of the above claim(s) 21-25,30-45,361 and 363 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 164-168,173-180,182-185,362 and 364 is/are rejected.
- 7) ☒ Claim(s) 181 and 186-188 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/30/09; 10/5/09; 1/15/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 164 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 164 – 168, 173 – 188, and 364 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 164 is unclear as to what fluctuation of the atrial contractility is considered sufficient to reduce a risk of an occurrence of a thromboembolic event.

Claims 165, 167, 173, 174, 176 – 179, and 181 – 188 recite the limitation "configuring the current." There is insufficient antecedent basis for this limitation in the claim. These should be amended to reflect the amendment made to claim 164.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 164, 165, and 167 rejected under 35 U.S.C. 103(a) as being unpatentable over Morillo et al. ("Chronic Rapid Atrial Pacing").

Regarding **claims 164, 165, and 167**, Morillo discloses applying an electrical current to the heart and modulating the current to cause fluctuation in atrial contractility sufficiently to reduce a risk of an occurrence of a thromboembolic event (e.g. page 3, 1st paragraph of Introduction and Figure 1). It is noted that because Morillo teaches maintaining Atrial Fibrillation that the electrical stimulation causes fluctuation in atrial contractility sufficient to reduce a risk of an occurrence of a thromboembolic event. Furthermore, blood flow within an atrium would necessarily be modified and increased out of a left atrial auricle during atrial fibrillation. It is well known in the art to apply stimulation to the vagus nerve in order to control the contractility of the heart. Furthermore, Morillo teaches that stimulation of the vagus nerve is known in the introduction. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modulated current applied to the heart as

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taught by Morillo with a stimulation applied to the vagus nerve as is known in the art and taught by Morillo, since such a modification would provide the predictable results of implanting a stimulator in a less invasive manner without having to make direct contact with the heart.

7. Claims 166, 168, and 361 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morillo et al. in view of Webster, Jr. et al. (USPN 6,292,695).

Regarding **claims 166, 168, and 361**, Morillo discloses the claimed invention except for identifying that a subject is suffering from AF and applying the current responsively to the detecting. Webster teaches that it is known use an AF sensor to detect AF delivery electrical stimulation responsive thereto (e.g. column 7, lines 1 – 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Morillo with the sensing of AF as taught by Webster, since such a modification would provide the predictable results of treating a patient as soon as the patient suffers from AF by stimulating a known and accessible nerve.

8. Claims 173 and 174 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morillo et al. in view of Gross et al. (US PG PUB 2003/0045909).

Regarding **claims 173 and 174**, Morillo discloses the claimed invention except for the control unit is configured to configure the current to include a stimulating current, which is capable of inducing action potentials in a first set and a second set of nerve

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fibers of the vagus nerve, and an inhibiting current, which is capable of inhibiting the induced action potentials traveling in the second set of nerve fibers in an afferent direction toward a brain of the subject, the nerve fibers in the second set having generally larger diameters than the nerve fibers in the first set, and wherein the control unit is configured to drive the electrode device to apply the stimulating current and the inhibiting current to the vagus nerve. Gross teaches that it is known to use a control unit that is configured to configure the current to include a stimulating current, which is capable of inducing action potentials in a first set and a second set of nerve fibers of the vagus nerve, and an inhibiting current, which is capable of inhibiting the induced action potentials traveling in the second set of nerve fibers in an afferent direction toward a brain of the subject, the nerve fibers in the second set having generally larger diameters than the nerve fibers in the first set, and wherein the control unit is configured to drive the electrode device to apply the stimulating current and the inhibiting current to the vagus nerve (e.g. paragraphs 59 – 60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the current as taught by Morillo with one that induces action potentials in some nerve fibers and inhibits action potentials in other nerve fibers as taught by Gross, since such a modification would provide the predictable results of minimizing any unintended side effects that an unblocked signal would have on other parts of the body.

9. Claims 175, 178, 179, 180, 182, 185, and 364 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morillo et al. in view of Osorio et al. (U.S.

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Patent 6,341,236).

Regarding **claims 175, 180, and 364**, Morillo discloses the claimed invention except for the control unit is configured to: during a first stimulation period, configure the current to cause a reduction in a force of contraction of atrial cells of the subject, and during a second stimulation period, configure the current to cause an increase in the reduced force of contraction of the atrial cells, by driving. Osorio teaches that it is known to drive the electrode device to apply the current during the first stimulation period, and withhold the electrode device from applying the current during the second stimulation period, which would cause a reduction in a force of contraction of atrial cells of the subject during the first period and an increase in the reduced force of contraction of the atrial cells during the second period (e.g. column 10, lines 16 – 20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation periods as taught by Morillo with the stimulation periods as taught by Osorio, since such a modification would provide the predictable results of adjusting the vagus nerve stimulation in an efficient manner in order to optimize therapeutic delivery and maximize cardiac output.

It is noted that the “off” period is a second stimulation period because it works directly with the “on” period and has a direct effect on the overall stimulation. As taught in column 9, lines 50 – 55, Osorio teaches that the device does cycle between “on” and “off” phases. Because these phases are the same as the high phase and low phase (i.e. no stimulation) as taught in pages 53 and 54 of the specification of the present application, this cycling would necessarily cause a reduction in a force of contraction of

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atrial cells during the first period, and an increase in the reduced force of contraction of the atrial cells during the second period.

Regarding **claims 178 and 179**, Morillo discloses the claimed invention except for the control unit is configured to configure the current to have a first frequency and amplitude during the first stimulation period, and a second frequency and amplitude during the second stimulation period, the first frequency greater than the second frequency. Osorio teaches that it is known that the control unit is configured to configure the current to have a first frequency and amplitude during the first stimulation period, and a second frequency and amplitude during the second stimulation period, the first frequency greater than the second frequency (e.g. column 5, lines 16 – 21). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation periods as taught by Morillo with the stimulation periods as taught by Osorio, since such a modification would provide the predictable results of adjusting the vagus nerve stimulation in an efficient manner in order to optimize therapeutic delivery and maximize cardiac output.

Regarding **claim 182**, Morillo discloses the claimed invention except for the control unit is configured to configure the current so as to induce action potentials in the vagus nerve during the first and the second stimulation periods. Osorio teaches that it is known that the control unit is configured to configure the current so as to induce action potentials in the vagus nerve during the first and the second stimulation periods (e.g. column 7, lines 62 – 65 and column 5, lines 23 – 24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

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stimulation periods as taught by Morillo with the stimulation periods as taught by Osorio, since such a modification would provide the predictable results of adjusting the vagus nerve stimulation in an efficient manner in order to optimize therapeutic delivery and maximize cardiac output.

Regarding **claim 185**, Morillo discloses the claimed invention except a sensor, configured to sense at least one physiological variable of the subject, and to generate a sensor signal responsive thereto, and wherein the control unit is configured to receive the sensor signal and to synchronize therewith a commencement of at least one of the first and second stimulation periods. Osorio teaches that it is known to use a sensor, configured to sense at least one physiological variable of the subject, and to generate a sensor signal responsive thereto, and wherein the control unit is configured to receive the sensor signal and to synchronize therewith a commencement of at least one of the first and second stimulation periods (e.g. column 4, lines 53 – 57 and column 5, lines 13 – 16). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Morillo with the sensor coupled to the stimulator as taught by Osorio, since such a modification would provide the predictable results creating closed loop circuitry related to the sensor signal and thus optimizing the therapeutic delivery by quickly and automatically delivering the stimulation in response to the sensed signal.

10. Claims 183 and 184 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morillo et al. in view of Osorio et al. as applied to claim 175 above, and further in

view of Stoop et al. (USPN 6,256,537).

Regarding **claims 183 and 184**, Morillo in view of Osorio discloses the claimed invention except for the control unit is configured to: drive the electrode device to apply the current in respective bursts in each of a plurality of cardiac cycles of the subject, and configure each pulse of each of the bursts to have a pulse width of at least a first pulse width and a number of pulses of at least a first number of pulses during the first stimulation period, and to have a pulse width of less than a second pulse width and a number of pulses less than a second number of pulses during the second stimulation period, the first pulse width being greater than or equal to the second pulse width and the first number of pulses being greater than or equal to the second number of pulses. Stoop teaches that it is known to alter the number and pulse width from burst to burst (e.g. column 8, lines 23 – 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation as taught Morillo in view of Osorio with the pulse bursts as taught by Stoop, since such a modification would provide the predictable results of optimizing therapeutic delivery to the atrial cells and thus increase blood flow within the atrium and throughout the heart.

Allowable Subject Matter

11. Claims 181 and 186 – 188 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is (571)270-1895. The examiner can normally be reached on M-F, 8:00 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. D./
Examiner, Art Unit 3762

/Scott M. Getzow/
Primary Examiner, Art Unit 3762